



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,708	05/03/2005	Michael Birsha Davies	P33143USW	6207
23347	7590	01/02/2008		
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B475 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER OSTRUP, CLINTON T	
			ART UNIT 3771	PAPER NUMBER
			NOTIFICATION DATE 01/02/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM  
ROSALIE.M.CHAMBERLAIN@GSK.COM  
JULIE.D.MCFALLS@GSK.COM

H

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,708	<b>Applicant(s)</b> DAVIES ET AL.	
	<b>Examiner</b> Clinton Ostrup	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☒ Claim(s) 4 & 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>05/03/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-33 are pending in this application.

#### ***Priority***

The examiner acknowledges this application was filed as a United States National Phase Application of International Application Serial No. PCT/EP2003/012435 filed November 5, 2003, which claims priority from Great Britain Application No. 0226021.4, filed November 7, 2002.

#### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The use of the trademarks has been noted in this application. For example, the trademark BECONASE® appears on page 1, line 24. Trademarks should be capitalized wherever they appears and be accompanied by their generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

#### ***Claim Objections***

Claims 4 and 17 are objected to because of the following informalities:

Claim 4 recites the limitation "the interengagement" in line 1, however, there is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "the detent mechanism" in lines 2-3, however, there is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "the reading feature" in line 4, however, there is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-3, 6, 8-13, 16, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Dmitrovic et al., (WO 98/30262).**

Dmitrovic et al., teach a container (Figure 3) having a first part (59) and a second part (63) and a hinge (64) through which the first and second parts are hingeably connected so that the parts are hingeable relative to one another between a first position which places the container in a closed state and a second position which places the container in an open state, and wherein the first and second parts are pivotally connected so that the parts are able to be pivoted relative to one another to different angular positions. See: page 10, line 16 – page 11, line 5; Figures 3-8; and abstract.

Dmitrovic et al., show the first and second parts as being closed (Figure 3) with a ridge portion on (80) for locking the container in a closed state, thus meeting the limitations of claims 2, 3, and 6.

In regard to claims 8-12 & 19, Dmitrovic et al., shows that the second part (63) as being pivotally hinged to the first part (59). The Dmitrovic et al., reference teaches that

Art Unit: 3771

the hinge is statically mounted to the first part (59) and pivotally mounted to the second part (63) and that the first and second parts can pivot and rotate around the container (Figure 4). Dmitrovic et al., teach moving the second part to both an open and a closed state and that in use, the open position, the second part (63) is rotated to the side of the container (Figure 5) to allow administration of the drug contained within the container.

See: page 4, line 21 -page 5, line 8 and page 11, line 23 – page 12, line 9.

Dmitrovic et al., teach that the lower body assembly (59) engages a stop and will not move any further when the recess is correctly aligned, thus teaching a nesting state as claimed in claim 13 and a detent mechanism as claimed in claim 16.

Dmitrovic et al., teach that the drug is contained in an inner part (56) and that the inner part (56) is adapted to hold the product in the container, thus meeting the specific limitations of claim 19. See: page 4, line 21 - page 5, line 21.

Therefore, the Dmitrovic et al., reference clearly teaches the container as claimed in claims 1-3, 6, 8-13, 16, and 19.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 4, 5, 7, 21, 24-27, and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howlett (6,062,214) and further in view of Dmitrovic et al., (WO 98/30262) as applied to claims 1-3, 6, 8-13, 16 and 19 above.**

Howlett teaches an inhaler for the aerosolized dispersion of medicaments. The primary reference teaches an inhaler comprising a housing (11) for receiving a pressurized dispensing container (12) and a mouthpiece (14) with a flexible hinged cover (15) that can potentially come into contact with the face of the user during normal use. See: figure 3. The primary reference teaches the lip of the cover (15) making contact with the lip of the mouthpiece (14) to close and protect the mouth piece. See: Col. 2, lines 55-65; col. 3, lines 17-21 and Figure 1. However, the reference lacks the specific hinge claimed as claimed in claims 21, 24-27 and 30-33.

Dmitrovic et al., teach a container (Figure 3) having a first part (59) and a second part (63) and a hinge (64) through which the first and second parts are hingeably connected so that the parts are hingeable relative to one another between a first position which places the container in a closed state and a second position which places the container in an open state, and wherein the first and second parts are pivotally connected so that the parts are able to be pivoted relative to one another to different angular positions. See: page 10, line 16 – page 11, line 5; Figures 3-8; and abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the aerosol housing with a mouthpiece cover as taught by Howlett, by using the hinged cover as taught by Dmitrovic et al., because of the reasonable expectation of obtaining a cover that would not come into contact with the face of the user during regular use.

**Claims 14, 15, 17, 18 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howlett (6,062,214) taken together with Dmitrovic et al., (WO 98/30262) and further in view of Rand et al., (WO 98/56444).**

The combined references above teach a container for holding an aerosol that has a cover that can be opened and pivoted in a manner to prevent contamination during normal use, as described above; however, the combination of references lacks the specific teaching of providing a container with reading feature and dose counter as claimed in claims 14, 15, 17, 18 and 29 or the intranasal dispenser as claimed in claim 28.

Rand et al., teach an inhaler comprising an external housing (1) with counter mechanism (13) and a window for viewing said counter mechanism through the rear of the housing (20). The Rand et al., reference teaches that the dispensing mechanism is useful in the treatment of respiratory disorders and that the counter allows the user to view the number of doses remaining in the container before the contents have been exhausted. Moreover, the Rand et al., reference teaches that metered dose inhalers are well known for delivering medicaments to the mouth and the nose for treatment of respiratory disorders. See: page 1, lines 1-34; page 4, lines 1-9; page 5, lines 24-35; page 6, lines 26-33 and Figures 1 and 7.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the aerosol device as taught by the combined references above by adding a viewing window for reading the number of doses remaining in the inhaler, as taught by Rand et al., because of the reasonable

Art Unit: 3771


expectation of obtaining an inhaler which provides a user with information about the remaining life of the product.


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (571) 272-5559. The examiner can normally be reached on M-F 7:30-5 pm with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Clinton Ostrup  
Examiner  
Art Unit 3771

  
JUSTINE R. YU  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700

12/21/07